



## CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**STUDY TITLE:** Split-belt treadmill training to rehabilitate freezing of gait and balance in Parkinson's Disease

**INVESTIGATOR/STUDY DOCTOR:** Dr. Alfonso Fasano

**CONTACT NUMBER (AVAILABLE 24 HOURS):**

Please call 416-603-5800, ext 5961 or 416-340-3155, and ask to page Dr. Alfonso Fasano

### INTRODUCTION:

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish, including your friends, family, and family doctor. Participation in this study is voluntary.

### BACKGROUND/PURPOSE:

You are being asked to participate in this study because you have Parkinson's disease (PD) with difficulty walking, specifically problems with your balance and episodes of "freezing" (where your feet feel "glued" to the floor and your legs shake for several seconds). Balance issues and "freezing" during walking in Parkinson's Disease happens because the legs move slowly and at different speeds. This can also make turning difficult. These problems can increase the risk of falls, which can result in injury (eg. hip fracture, cuts, bruises, etc) and further disability (eg. fear of walking, requiring nursing home care, etc).

Freezing and balance problems are managed with Parkinson's medications, deep brain stimulation and physiotherapy. Treadmill training is currently being used by physiotherapists to improve walking speed and balance in people with PD. However, there is currently no way to fully treat the episodes of "freezing" that people with PD experience when walking.

The split-belt treadmill (SBTM), which is a treadmill that has 2 belts that move at different speeds, may be able to train the legs to walk at the same speed. This is called "adaptation." Adaptation is when we teach the body to adjust itself by making the changes in the environment that it is in.

SBTM has been shown to improve walking in people who have leg weakness from a prior stroke for up to 3 months. However, SBTM has not previously been studied in people with PD. From

previous studies in stroke patients, the longer people did SBTM training, the longer the results lasted.

**The purpose** of this study is to compare how SBTM training and traditional treadmill training (TM) affects the “freezing” that people with PD experience while they walk. We will also want to see how long these effects last. When SBTM training was used for 6 weeks in stroke patients, improvements in walking could be seen for 3 months. We will be using a similar program to see if this will benefit PD patients as well.

Up to 28 participants will take part in this study at UHN and all study appointments will be completed within 7.5 months.

### STUDY DESIGN:

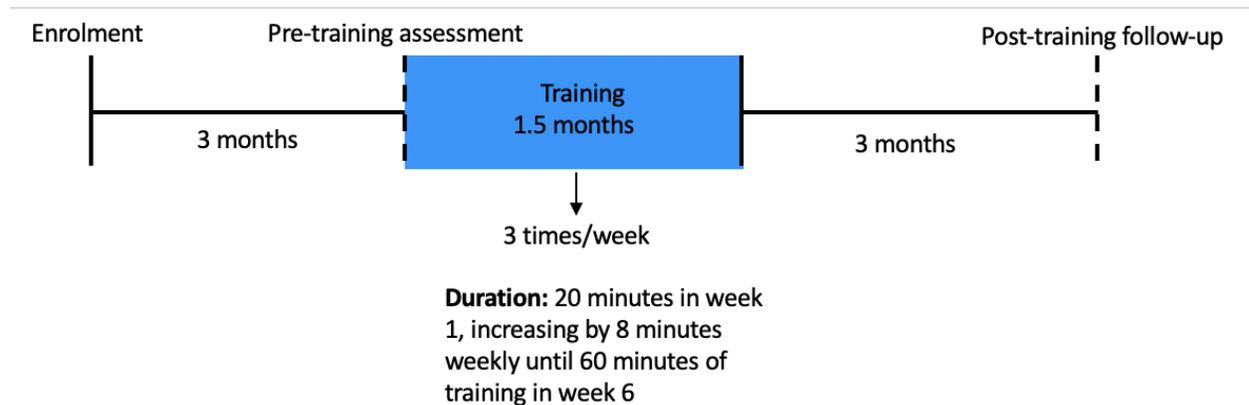
This is a randomized study. If you decide to participate you will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor your doctor can choose what group you will be in. You will have a 50/50 chance of being placed in either group.

- SBTM Training Group, where the belts move at different speeds  
OR
- TM Training Group, where the belts will move at the same speed.

### STUDY VISITS AND PROCEDURES:

If you choose to take part in this study, you will receive treadmill training in addition to your current standard of care management for your PD. All the appointments will take place at Toronto Western Hospital. You will be in this study for approximately 7.5 months (refer to Figure 1).

The study has 3 main parts: 1) Pre-training 2) Training period 3) Post-training follow-up.



**Figure 1:** Timeline of the study

We will also look at your medical chart to collect information about your medical history, demographics (your age and gender), and the medications you are taking. This information will be used for study purposes only.

1. **Pre-training (3 months):**

**Falls calendar:** Either you or your caregiver will document falls in a calendar which will be provided to you. This calendar allows you to track and describe your falls. You will be asked to record your falls for 3-months prior to beginning the treadmill training.

**Pre-training assessment:**

- Clinical assessment of gait: At this appointment, you will see a doctor who will assess your walking and check the severity of your PD.
- Questionnaires: You will also fill out questionnaires to help us better understand why you are falling and your quality of life. You will also be asked to complete a short 6-meter walk test so that we can see how you walk.

**Gait Mat:** Prior to the first session, we will measure the speed of your walking with the 6-meter gait mat. This will allow us to match the treadmill speed to your normal walking speed. You will also walk on the 6-meter gait mat at the end of your last session, so that we can see how you walk on after your training.

2. **Training period (6 weeks):** You will be randomized into either the TM training or SBTM training group. If you are in the SBTM group, the only difference is that one belt of the treadmill will move 25% slower than the other. The belt that will move slower is determined by which side of your body is more affected by PD.

**Training Sessions:** These sessions will take place 3 times a week for 6 weeks, and will be no longer than 1 hour each time. However, the actual time that you will spend at each appointment can last up to 1.5 hours, to account for the time it will take you to get used to walking on the treadmill and the rest periods that you will receive. To prevent falling on the treadmill, you will be attached to a harness while you walk (refer to Figure 2B).

The duration of the training period will start at 20 minutes in the first week, and slowly increase each week (by 8 minutes) until you reach 60 minutes of training by Week 6. All 3 sessions in the week will have the same duration of training (eg. all three sessions in the first week will be for 20 minutes). The speed of the treadmill will remain the same for the entire 6-week training period.

If you have any difficulty keeping up with these sessions, your training duration will be adjusted to the most recently tolerated session. This means that if you cannot tolerate walking for 28 minutes in Week 2, we will adjust the training to back to 20 minutes from the week before.

Rest breaks are included in the training sessions, but you may also request a rest period at any time.

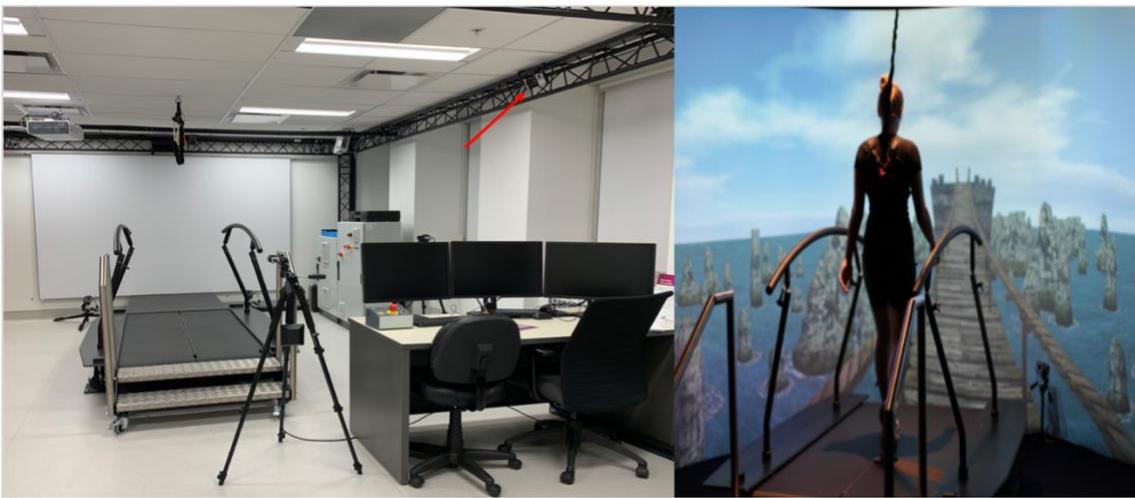
If you are concerned about not having the energy or stamina to participate in this study, please speak to your doctor or contact the number provided in this consent form.

**Falls Calendar:** You will continue to track your falls for the duration of the study. During each training session, the study coordinator will review your falls calendar to see how frequently you are falling at home.

3. **Post-training (3 months):**

**Falls Calendar:** Again, you will continue to document your falls in the calendar provided to you at the beginning of the study.

**Post-training follow-up:** This appointment will take place 3 months after your training, and will be identical to your pre-training assessment. You will see a doctor who will assess your walking and check the severity of your PD, and you will fill out questionnaires and walk on the 6-meter gait mat.



**Figure 2:** *Treadmill training with the virtual reality system. A) The gait lab, featuring the treadmill, virtual reality screen. B) Simulation of a subject walking on the treadmill, while attached to a harness to prevent falls.*

This is a summary of the tests you will have during the course of the study:

	Falls documentation	Pre-training assessment	Training Week 1	Training Week 2	Training Week 3	Training Week 4	Training Week 5	Training Week 6	Falls documentation	Post-training follow-up
Timeline (T)		T=3 months						T=4.5 months		T=7.5 months
Clinical assessment of gait		X								X
Questionnaires		X								X
Falls calendar	X	X	X	X	X	X	X	X	X	X
6-meter gait mat		X						X (only at the end of the last session)		X
Treadmill training										

## **Video Recordings**

We will take videos of your walking during the 6-meter gait mat analysis and treadmill training. Video recordings may include your entire body, but all personal identifiers (such as your face) will be blurred or blackened out.

Video recording is mandatory as the videos will be used for the analysis and review of this study. The videos will be kept in a locked and secure area at Toronto Western Hospital, and will be deleted after 10 years.

We would also like the opportunity to use the video recordings for scientific presentations or for education purposes. We will ask for your permission to use these recordings at the end of this consent form.

## RISKS:

Taking part in this study has risks. Some of these risks we know about. There is also a possibility of risks that we do not know about. Please call the study doctor if you have any side effects even if you do not think it has anything to do with this study.

Risk of Treadmill Training: Treadmill training may cause you to feel fatigued. You can request a rest period at any time.

## BENEFITS:

You may experience some physical benefit from being in the study as treadmill training is used by physiotherapists outside the hospital (i.e. to help improve movement and reduce stiffness from the PD).

Information learned from this study may help determine additional rehabilitation options for patients with PD.

## CONFIDENTIALITY:

Your data will be shared as described in this consent form or as required by law. All personal information such as your name, address, phone number, OHIP number, and family physician's name will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept by the study doctor in a secure place, separate from your file.

## **Personal Health Information**

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name
- address
- year of birth
- new or existing medical records that includes types, dates and results of medical tests or procedures

Representatives of the University Health Network (UHN) including the UHN Research Ethics Board may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines.

The study doctor will keep any personal health information about you in a secure and confidential location for 10 years.

Your participation in this study also may be recorded in your medical record at this hospital. This is for clinical safety purposes.

#### Research Information in Shared Clinical Records

If you participate in this study, information about you from this research project may be stored in your hospital file and in the UHN computer system. The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at [privacy@uhn.ca](mailto:privacy@uhn.ca)).

You will not be named in any reports, publications, or presentations that may come from this study.

#### VOLUNTARY PARTICIPATION:

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your care. We will give you new information that is learned during the study that might affect your decision to stay in the study.

#### WITHDRAWAL FROM STUDY:

If you decide to leave the study, you have the right to request withdrawal of information collected about you, including the video recordings. Let your doctor or study coordinator know.

If you leave the study, the information that was collected before you left the study will still be used in order to help answer the research question. No new information will be collected without your permission.

#### COSTS:

You will not have to pay for any of the procedures involved in this study. There is no reimbursement or payment for participating in this study.

#### CONFLICT OF INTEREST:

Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

#### RIGHTS AS A PARTICIPANT:

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

**QUESTIONS ABOUT THE STUDY**

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Dr. Fasano, the Principal Investigator of this study, at +1(416)603-5800 ext 5961. If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.

**CONSENT**

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

I allow the use of videos taken during this study for publication and teaching purposes:

YES  NO

\_\_\_\_\_  
Print Study Participant's Name

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

\_\_\_\_\_  
Print Name of Person Obtaining Consent

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**Was the participant assisted during the consent process?  YES  NO**

If YES, please check the relevant box and complete the signature space below:

The person signing below acted as an interpreter for the participant during the consent process and attests that the study as set out in this form was accurately interpreted has had any questions answered.

\_\_\_\_\_  
Print Name of Interpreter

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship to Participant

\_\_\_\_\_  
Language

- The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

\_\_\_\_\_  
Print Name of Witness

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship to Participant